

REMARKS

Claims 1-3, 7-10, 66-68 and 72-81 are pending in the application.

Claims 1-3, 7-10, 66-68 and 72-81 stand rejected.

Applicants reply within the two-month shortened statutory period to receive an Advisory Action.

Claim Rejections – 35 USC § 112

Claims 1-3, 7-10 and 76-78 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Claims 66-68, 72-75 and 79-81 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Applicants amend claims 1 and 66 to include the “introducer” as suggested by the Examiner and submit that these claims are allowable as amended.

Claims 2, 3, 7-10 and 76-78 depend from claim 1 and claims 67, 68, 72-75 and 79-81 depend from claim 66 and thus, are allowable for similar reasons.

Claims 3, 7 and 77 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Applicants amend claims 3, 7 and 77 to clarify the antecedent bases.

Claim Rejections – 35 USC § 102

Claims 66-68 and 73-74 stand rejected under 35 U.S.C. 102(b) as being anticipated by WO 93/04724 to Brennen et al. (“Brennen”). Applicants amend claim 66.

The Office Action contends that claim 66 is anticipated by the manually steerable stylet of Brennan as being “fully capable of being inserted into any other physical entity where the entrance diameter is less than the diameter of the circle formed by the stop member 32 [to] eventually form the loop illustrated in Fig. 14.” (Office Action page 5). There is simply nothing in Brennen to support the argument that Brennan’s stylet would automatically form a loop if inserted into a known introducer. Brennen’s device is not configured to form a loop upon insertion into an introducer nor could it be used in this fashion.

Brennan discloses, at most, a “steerable stylet and manipulative handle assembly especially adapted for guiding” the stylet through passages in a body. (Abstract). Brennen’s device requires complex manual manipulation of a manipulable handle by a practitioner to curve and steer the stylet. In contrast, Applicants’ catheter is configured such that *mere insertion* of the catheter into the introducer is *sufficient to form a loop* to hold the catheter in a body cavity.

Claim 66, as amended, recites the structural limitation of a catheter “wherein the protruding member and first and second elongate members are configured such that sliding of the first elongate member relative to the protruding member *upon insertion of the catheter into an introducer pulls the second elongate member to form a loop* in the distal region of the first elongate member.” (emphasis added). Brennen does not disclose this structural configuration and Applicants maintain that claim 66 is allowable over Brennan.

Claims 67-68 and 73-74 depend from claim 66 and are allowable for similar reasons.

Accordingly, Applicants request the withdrawal of the rejection of the claims under Section 102.

Claim Rejections – 35 USC § 103

Claims 1-3, 8-10 and 76-78 stand rejected under 35 U.S.C. 103(a) as being obvious over Brennan in view of U.S. Pub. No. 2001/0044625 to Hata et al. (“Hata”).

Claims 79 and 81 stand rejected under 35 U.S.C. 103(a) as being obvious over Brennen.

Claim 7 stands rejected under 35 U.S.C. 103(a) as being obvious over Brennen in view of Hata as applied to claim 1 above, and further in view of U.S. Pat. No. 4,906,230 to Maloney et al. (“Maloney”).

Claim 72 stands rejected under 35 U.S.C. 103(a) as being obvious over Brennen in view of Maloney.

The Examiner asserts that Brennen’s “catheter is fully capable of being inserted into any other physical entity where the entrance diameter is less than the diameter of the circle formed by the stop member 32, and the insertion of the catheter will cause the stop member to abut the entryway of the other entity, which will in turn cause a pulling of the wire . . . to eventually form the loop.” (Office Action pages 9-10).

Claim 1, as amended, recites the structural limitation of a catheter “configured such that inserting the tubular catheter body into an introducer causes interaction between the stop member

and the introducer to pull the elongate member to form a loop in the distal region of the tubular catheter body.” There is simply nothing in Brennen that suggests, as argued by the Examiner, that Brennan’s stylet would automatically form a loop if inserted into an introducer. Brennen’s device is not configured to form a loop upon insertion into an introducer nor could it be used in this fashion.

The very purpose of manual manipulation and steering of Brennen’s device would be lost if the device handle were shrunk to the nominal diameter of known introducers. It would also be hard to imagine that practitioners would seek to enlarge introducer diameters to the size of Brennan’s handle. Rather, the handle body of Brennen would simply impede insertion into an introducer at a certain point, without formation of a loop absent additional manual manipulation of the steering mechanisms. Brennen’s product would not have inherently allowed automatic loop formation in any use for which it was intended and one of ordinary skill would not conceive of shoving Brennen’s device into a known introducer to cause this to happen.

Applicants maintain that one of ordinary skill in the art in possession of Brennen would not be motivated to modify Brennen as suggested by the examiner with any reasonable expectation of forming a loop without additional manual manipulation. Brennen’s disclosure is directed entirely to manual manipulation and so would not lead one of ordinary skill in the art to seek to form a curve or loop with the device without such manual manipulation.

Accordingly, Applicants submit that claim 1 is allowable over Brennan. Claims 2-3, 7-10 and 76-78 are dependent on claim 1 and are allowable for similar reasons, in addition to their own respective features. For example, Claim 76 further clarifies that it is “*interaction between the stop member and the introducer [that] pull[s] the elongate member to form the loop.*” (emphasis added). The Office Action recognizes that the combined references do “not teach inserting the tubular catheter body into an introducer that causes interaction between the stop member and the introducer to pull the elongate member to form the loop in the distal region of the tubular catheter body.” (page 11). Mere use of known introducers with a device capable of forming a loop still does not obtain a device in which “*interaction between the stop member and the introducer [that] pull[s] the elongate member to form the loop*” as recited in claim 76.

It is further noted that the introducer is not removed but provides continued interaction with the stop member to maintain the formed loop. Also, conventional use of known

introducers, which are admittedly removed after insertion, would defeat the purpose of Applicants invention, that of formation and maintenance of a loop.

Applicants amend claim 79 to clarify that the introducer remains in place to maintain the loop formed by interaction with the introducer. The known introducers referenced in the Office action are removed upon insertion of the catheter into a body cavity.

Regarding claim 66, the Examiner suggests that "introducers for gently inserting and placing catheters . . . are well known in the art [and that it] would be obvious . . . to modify the device of Brennen so as to include an introducer with a reasonable expectation of success to [insert] the catheter." (Office Action page 8). Applicants' catheter is not configured merely for introduction with an introducer, however, but for specific interaction with an introducer to automatically form a loop.

Applicants are not claiming mere insertion of a catheter using an introducer, but rather a catheter configured such that "sliding of the first elongate member relative to the protruding member upon [mere] insertion of the catheter into an introducer pulls the second elongate member to form a loop in the distal region of the first elongate member," as recited in amended claim 66. As discussed with regard to claim 1, there is simply nothing in the cited references that discloses or suggests configuration of a catheter for such interaction.

Accordingly, Applicants maintain that claim 66 is allowable over the cited references.

Claims 72, 79 and 81 depend from claim 66 and are allowable for similar reasons, in addition to their own respective features. For example, regarding claim 81, the Examiner asserts that pigtail loops are known in the art, however, there has been no showing that loops of any kind are known to be formed merely by insertion of the catheter into an introducer or that any known device could be so employed with a reasonable expectation of success as to automatic formation of a loop by mere interaction with an introducer.

Accordingly, Applicants request the withdrawal of the rejection of the claims under Section 103.


CONCLUSION

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reason for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to amendment. Applicants respectfully request consideration of all filed IDS' not previously considered, by initialing and returning each Form 1449.

No charges are believed due. However, if any fees are due, they are being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization. Please apply all charges or credits to Deposit Account No. 06-1050, referencing Attorney Docket No. 12389-004001.

Respectfully submitted,

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